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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/031,087	02/26/98	CHIANG C	CLES 005

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EXAMINER	
TUNG, J	

ART UNIT	PAPER NUMBER
1634	4

DATE MAILED: 03/19/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/031,087	Applicant(s) Chiang et al.
	Examiner Joyce Tung	Group Art Unit 1634

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-12 is/are pending in the application.

Of the above, claim(s) 12 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-11 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-12 are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

☒ notice to comply

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Claim Objections

1. The numbering of claims is not accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 5-13 have been renumbered as claims 4-12.

Election/Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-11, drawn to a method for monitoring nucleic acid amplification using complementary probes in which one probe is labeled with fluorophore and another is labeled with quencher, classified in class 435, subclass 91.2.

II. Claim 12, drawn to a method to detect a specific nucleic acid in a prepared nucleic acid sample, classified in class 435, subclass 6.

3. Inventions I and II are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention I has separate utility such as monitoring amplification of a target sequence. See MPEP § 806.05(d).

4. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

5. During a telephone conversation with Mr. James M Kanage on 2/19/99 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-11. Affirmation of this election must be made by applicant in replying to this Office action. Claim 12 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Sequence Rules

7. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

APPLICANT IS GIVEN THE RESPONSE PERIOD SET FORTH IN THIS OFFICE ACTION WITHIN WHICH TO COMPLY WITH THE SEQUENCE RULES, 37 CFR 1.821-1.825. Failure to comply with these requirements will result in **ABANDONMENT** of the application under 37 CFR 1.821(g).

In specification, the sequences in table I, II and III on page 8 are required to have SEQ ID NO.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9 Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 1-11 are vague and indefinite because it is not clear how the second shorter oligonucleotide probe is compared to which oligonucleotide.

b. Claims 1-11 are vague and indefinite because the longer probe in claim 1 has no antecedent basis.

c. Claim 2 is vague and indefinite because the language "the nucleic acid polymerase" has no antecedent basis from where it is recited.

d. Claims 1-11 are vague and indefinite because it is not clear how amplification is carried out using any method with using a first oligonucleotide probe and a second shorter oligonucleotide probe without requiring at least one primer. Are the probes meant to be primers? It is suggested to clarify the uncertainty.

e. Claims 1-11 are vague and indefinite because of the language "at least about". It is not clear whether the limitation defines a lower limit via "at least" or whether it defines either an upper or lower limit via "about". It is suggested to clarify the metes and bounds of the length variation?

f. Claims 1-11 are vague and indefinite because of the language "varying in length". It is not clear how the second shorter oligonucleotide probe is varying in length. Does the probe vary over time or vary due to amplification. It is suggested to clarify the uncertainty.

g. Claim 3 is vague and indefinite because of the language "the same hybridized base pair". It is not clear how the fluorophore on the first probe and the quencher molecule on the second probe are on the same hybridized base pair. It is suggested to clarify the uncertainty.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has

fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

11. Claims 1-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Cesare (5,716,784).

Cesare discloses an improved assay to detect or measure target nucleic acid sequence replication in a thermal PCR amplification procedure. The assay uses an analytical probe labeled with an energy transfer donor fluorophore at 5' terminal, a detection probe labeled with an energy transfer acceptor fluorophore at 3' terminal and the result is determined by energy transfer measurement (see column 2, lines 24-58) which provides a measure of amount of target nucleic acid amplified in PCR (see column 2, lines 57-58). This is also a measure of degree of amplification of the target (see column 6, lines 50-51). The analytical probe hybridized to the target nucleic acid is longer than the detection probe by 16 nucleotides at 3' terminal which hybridizes to the analytical probe and the Tms of the analytical probe and detection probe are 69.8°C and 54.8°C (see column 6, lines 8-16) respectively. Fluorescence energy transfer between a donor and acceptor molecule can be highly efficient within close proximity about 50 Å.

The teachings of Cesare anticipate instant claims 1-11 in which a method is used to monitor nucleic acid thermal amplification on a target nucleic acid using a first probe and second probe. The first probe is hybridized to the target and labeled with fluorophore at 5' end and second probe is complementary to the first probe, and labeled with quencher at 3' end. The first probe and second probe are differ in length and Tm of two primers is different.

12. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

13. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1634 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

March 3, 1999

Ardin H. Marschel

ARDIN H. MARSCHEL
PRIMARY EXAMINER

Application No.: 09/031,087

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- [X] 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.
- [X] 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- [X] 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- [ ] 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- [ ] 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- [ ] 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- [ ] 7. Other: _____

Applicant Must Provide:

- [X] An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- [X] An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- [X] A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
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